DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 30 2012

Re: DATSCAN
Docket No.: FDA-2011-E-0367

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 5,310,912, filed by GE Healthcare Limited, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for DATSCAN (Ioflupane I-123 injection), the human drug product claimed by the patent.

The total length of the regulatory review period for DATSCAN (Ioflupane I-123 injection) is 677 days. Of this time, 0 days occurred during the testing phase and 677 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act (FFD&C Act) involving this drug product became effective: not applicable

   The applicant claims June 19, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that no IND was submitted under subsection 505(i) of the FFD&C Act for this human drug product.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the FFD&C Act: March 9, 2009.

   The applicant claims March 6, 2009, as the date the new drug application (NDA) for DATSCAN (NDA 22-454) was initially submitted. However, FDA records indicate that NDA 22-454 was submitted on March 9, 2009.

3. The date the application was approved: January 14, 2011.

   FDA has verified the applicant's claim that NDA 22-454 was approved on January 14, 2011.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Christine S. Lee, Ph.D., J.D.
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